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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,757	04/17/2001	Gary K. Owens	00148-03	4147
20350	7590	03/15/2004		
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER	
			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SPK

Office Action Summary

Application No.	09/807,757	Applicant(s)	OWENS ET AL.
Examiner	Daniel M Sullivan	Art Unit	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 December 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2,22,31-36 and 41-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 2,22,31-36,41-43,45,46 and 48 is/are allowed.
- 6) Claim(s) 47 is/are rejected.
- 7) Claim(s) 44 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: NOTICE TO COMPLY.

DETAILED ACTION

This Office Action is a reply to the "Amendment" of 19 December 2003 filed in response to the Non-Final Office Action mailed 1 October 2003. Claims 22-29 and 35-39 were withdrawn from consideration and claims 1-3, 5-10, 12, 13, 21, 30-34 and 40-42 were considered in the 1 October Office Action. Claims 1, 3, 5-10, 12-13, 21, 23-30 and 37-40 were canceled, claims 2, 22, 31-34, 36, and 41-42 were amended and claims 43-48 were added in the 19 December Paper. Claims 2, 22, 31-36, and 41-48 are pending and under consideration.

Response to Amendment

Rejection of claims 1, 3, 5-10, 12-13, 21, 23-30 and 37-40 is rendered moot by cancellation of the claims.

Claim Objections

Objection to claims 31-34 and 41-42 is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 101

Rejection of claims 41 and 42 under 35 U.S.C. 101 is withdrawn in view of the amendment of the claims such that they no longer encompass non-statutory subject matter.

Claim Rejections - 35 USC § 112

Rejection of claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn in view of the amendment of the claims such that they are limited to an isolated genetically engineered host cell comprising an isolated polynucleotide comprising the rat SM α -A promoter/enhancer.

Claim Rejections - 35 USC § 102

Rejection of claim 21 under 35 U.S.C. 102(b) as being anticipated by either one of Blank *et al.* (1992) *J. Biol. Chem.* 267: 984-989 as evidenced by NCBI Online, Nucleotide Sequence Accession No. S76011 (gi:242241) or Shimizu *et al.* 1995, *J. Biol. Chem.* 270:7631-7643 as evidenced by Blank *et al.* (*supra*) is withdrawn. The art of record does not teach or suggest an isolated nucleic acid comprising sufficient sequence from the SM α -A first intron to confer smooth muscle-cell specific expression *in vivo* and having the structural limitations of the claims.

Election/Restrictions

In the Remarks, Applicant requests reconsideration of the restriction requirement and rejoinder of the withdrawn claims on the grounds that the art, enablement and written description issues do not appear to be significantly different from those under consideration and therefore does not amount to an undue burden for the Examiner. This argument has been fully considered but is not deemed persuasive because, for the reasons set forth in the previous Office Action, the withdrawn subject matter is distinct from the claims presently under examination and would

require search and examination. Therefore, examination of the withdrawn claims in the present application would place an undue additional burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

New Grounds

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Amended claims 31 and 41 are directed to nucleic acids comprising variants of SEQ ID NO: 19 and 20. In the remarks, Applicant states, “[t]he Examiner will note that the rat sequences depicted in Figure 10B differ somewhat from the human sequences set forth in the sequence listing, therefore necessitating the nucleotide changes referred to in the claims” (page 5).

Applicant is reminded, MPEP 1.821(c) states, “[e]ach sequence disclosed must appear separately in the ‘Sequence Listing.’” It is clear from Applicant’s remarks that the rat sequences set forth in Figure 10B are not disclosed in the “Sequence Listing”. Therefore, the “Sequence Listing” does not comply with the rules. A complete response to this Office Action must include a substitute paper copy of the “Sequence Listing” and a CRF copy of the “Sequence Listing” which include

all of the sequences disclosed in the application, as well as the proper statements as indicated on the attached “Notice to Comply”.

Claim Objections

Claim 44 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 42. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

The MPEP states, “[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP § 2163.06). The MPEP further states,

“[w]henever the issue arises, the fundamental factual inquire is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application” (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

The instant claim 47 is directed to an isolated polynucleotide comprising various fragments of the sequence set forth as SEQ ID NO: 1 which were neither explicitly nor implicitly contemplated in the originally filed disclosure. Specifically, the original specification and claims do not contemplate a nucleic acid limited to comprising nucleotides 1-2605, 2011-2605 or 2011-5342 of SEQ ID NO: 1. Therefore the limitations constitute new matter. In the remarks, Applicant indicates that support for new claim 47 can be found in lines 25-28 of page 17 of the specification. However, the passage cited provides only “exemplary conditions of high stringency” and does not suggest a nucleic acid comprising any particular fragment of SEQ ID NO: 1.

Allowable Subject Matter

Claims 2, 22, 31-36, 41-43, 45, 46 and 48 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER